Serial No.: 10/648,162 Filed: August 26, 2003

Page 9 of 12

## **REMARKS**

# I. Status of the Claims

Claims 1-54 were pending in the application at the time of the Final Office Action dated September 13, 2006 (the "Action"). Claims 1-3, 5-9, 12-21, 25,26, 28-40, 42-46 and 49-54 stand rejected under 35 U.S.C. Section 103(a) as being unpatentable over Konta et al. (Significance of Discordant ST Alternans in Ventricular Fibrillation) ("Konta"). Claims 4, 27 and 41 stand rejected under 35 U.S.C. § being unpatentable over Konta in view of U.S. Patent No. 6,965,797 to Pastore et al. ("Pastore"). Claims 10, 11, 22-24, 47 and 48 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Konta in view of U.S. Patent No. 6,915,156 to Christini.

In response, independent Claims 1, 18 and 38 have been amended to generally incorporate the recitations of Claims 14, 19 and 50, respectively. Claims 13-14, 19-20 and 50-51 have been canceled. The above amendments generally rewrite Claims 14, 19 and 50 in independent form and therefore, do not present any new issues or require and additional search. Entry of the above amendments is respectfully requested.

Applicants respectfully submit that the pending claims are in condition for allowance for at least the reasons that follow.

# II. The Rejections Under 35 U.S.C. § 103

## A. Independent Claims 1, 18 and 38

Claim 1 recites a method for selectively initiating interventional therapy in a subject, including:

chronically detecting electrical activity in first and second cardiac regions in the subject;

identifying discordant alternans in at least one component of the detected electrical activity based on a comparison of the electrical activity in the first and second cardiac regions; and

initiating interventional therapy in the subject responsive to the identification of discordant alternans, wherein the electrical activity comprises an electrogram from internally implanted electrodes.

Serial No.: 10/648,162 Filed: August 26, 2003

Page 10 of 12

Claim 38 recites a computer program product corresponding generally to Claim 1. Claim 18 recites a system for selectively initiating interventional therapy in a subject including:

a plurality of electrodes configured and sized to chronically detect electrical activity in first and second cardiac regions; and a discordant alternans monitor operably associated with the electrodes, the discordant alternans monitor configured to identify discordant alternans in at least one component of the detected electrical activity based on a comparison of the electrical activity in the first and second cardiac regions; and to initiate interventional therapy in the subject responsive to the identification of discordant alternans, wherein the electrodes are configured to be internally implantable in the subject.

Applicants submit that Konta does not teach or suggest internally implanted electrodes for detecting discordant alternans. Konta discusses an experiment on dogs in which 60 electrodes are attached on the exposed pericardium of the dog. Konta, page 2185, col. 2. Konta makes no mention of internally implanted electrodes as recited in independent Claims 1, 18 and 38. As discussed in the Specification on page 3, line 30 to page 4, line 3, electrical activity for successive cardiac cycles can be detected from a system chronically implanted in a subject. In contrast, the 60 electrodes of Konta are attached through a sock to the epicardium and to the area covering the region of the entire left and right ventricles, and as noted in the Action, the pericardium of the dog is exposed. *Id.* In discussing clinical studies, Konta notes that a body surface electrocardiographic mapping technique could detect a discordant ST alternans; however, internally implanted electrodes are not mentioned by Konta. Therefore, Konta does not disclose all of the recitations of Claims 1, 18 and 38 as required by § 103.

In addition, there is no motivation to modify Konta to use internally implanted electrodes. The dogs used in the experiment described by Konta all had induced acute myocardial ischemia. Konta, page 2185, col. 2 and Abstract. Because Konta is focused on the discordance of ST alternans during acute myocardial ischemia and ventricular fibrillation, there is no motivation to chronically detect electrical activity in the heart using internally implanted electrodes as recited in Claims 1, 18 and 38.

Serial No.: 10/648,162 Filed: August 26, 2003

Page 11 of 12

Applicant submits that independent Claims 1, 18 and 38 are patentable at least for the reasons discussed above. Claims 2-12, 15-17, 21-37, 39-49, and 52-54 are patentable at least per the patentability of the claims from which they depend. Accordingly, Applicant requests that the rejections under § 103 be withdrawn.

In addition, various dependent claims are separately patentable for at least the reasons that follow.

# B. Claims 6, 29 and 43

Dependent Claims 6, 29 and 43 each recite initiating interventional therapy responsive to a change in the component of detected electrical activity from concordant to discordant alternans. Konta merely states that electrical alternans were suppressed by the drug verapamil, and does not teach or suggest initiating therapy responsive in a change from concordant to discordant alternans. Therefore, Claims 6, 29 and 43 are separately patentable.

# C. Claims 9, 32 and 46

Claims 9, 32 and 46 each recite that the interventional therapy reduces a risk of atrial arrhythmia. The dogs used in the experiment of Konta all had induced myocardial ischemia and some of the dogs exhibited ventricular fibrillation. Konta, page 2185, col. 1. However, Konta apparently does not discuss atrial arrhythmia, and therefore, reducing a risk of atrial arrhythmia is not disclosed by Konta. For at least these reasons, Claims 9, 32 and 56 are separately patentable.

## III. Conclusion

In view of the foregoing amendment and remarks, the Applicants respectfully request that all outstanding rejections to the claims be withdrawn and that a Notice of Allowance be issued in due course.

Serial No.: 10/648,162 Filed: August 26, 2003

Page 12 of 12

Respectfully submitted,

Laura M. Kelley

Registration No. 48,441 Attorney for Applicants

Myers Bigel Sibley & Sajovec, P.A.

P.O. Box 37428

Raleigh, North Carolina 27627

Telephone: 919/854-1400 Facsimile: 919/854-1401

## **CERTIFICATE OF MAILING**

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Mail Stop AF, Commissioner for Patents, PO Box 1450, Alexandria, VA 22313-1450, on December 12, 2006.